

### **REMARKS/ARGUMENTS**

Claims 1 and 39 are pending.

Citations to the Specification are directed to U.S. Patent Application Publication No. 2006/0128703 (Dodda Mohan Rao).

The Examiner's courtesy in granting an interview to Applicants' representative on September 29, 2009 is gratefully acknowledged. Applicants' separate record of the substance of the interview is incorporated into the following remarks.

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

### **Art Rejections**

Claims 1 and 39 stand rejected as anticipated over Barbachyn et al., U.S. Patent No. 5,688,792. Claims 1 and 39 stand rejected as anticipated over Meng. Claims 1 and 39 stand rejected as anticipated over Pearlman et al. Applicant respectfully traverses these rejections. Since the Examiner has previously considered these rejections together, they will be addressed together, herein.

With regard to the anticipation rejection, in Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the Barbachyn, Meng, or Pearlman reference.

Claim 1 is directed to a crystalline linezolid form III, characterized by an x-ray powder diffraction spectrum having peaks expressed as  $2\theta$  at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees, and further characterized by an IR spectrum having main bands at about 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and  $756\text{ cm}^{-1}$ , wherein there is at least a 99.8% enantiomeric excess of the linezolid form III.

In the Office Action of November 8, 2007, with regard to the rejections over Barbachyn, Meng, and Pearlman, the Examiner requested that Applicant provide a showing of how the instantly claimed crystalline form is different from the disclosures of Barbachyn, Meng, and Pearlman (see Office Action of November 8, 2008 at pages 5-6).

The Examiner argues that the information missing from the reference is inherently present, e.g. XRD pattern of a solid form. The Examiner admits that the reference is silent on this information, but sets forth that Applicant is requested to provide this information in order to show that the instantly claimed crystalline form is not the same as the one disclosed in the prior art. (Office Action of August 21, 2009 at page 2).

The Examiner further argues that IR data or melting point data are not sufficient to demonstrate that the instant form is a different crystalline form, and that Applicant is invited to provide XR data showing that the instant form is different in order to overcome the grounds of rejection. (Office Action of August 21, 2009 at page 3).

As shown in the Response of August 20, 2008, the art teaches that XRPD data is reliable to differentiate between different polymorphic crystalline forms, and that the art teaches that IR data is reliable to differentiate between crystalline polymorphic forms. Applicant has provided XRPD data and IR spectra for the claimed polymorphic form, and demonstrated that IR data show the polymorphic forms as taught in the Barbachyn, Meng, and Pearlman references are distinct from the claimed polymorphic form III linezolid.

Applicant submits herewith the Third Declaration under 1.132 of D. Mohan Rao, Ph.D., which sets forth that the methods as disclosed in the Barbachyn et al. reference do not produce the claimed linezolid polymorphic form III, based on a comparison of the XRPD data for the claimed linezolid polymorphic form III, and the XRPD data for the linezolid polymorphic form produced by the methods of Barbachyn. Using the methods described in the Barbachyn reference, Applicant prepared linezolid polymorphic form, and evaluated the linezolid polymorphic form produced using XRPD (see Declaration at ¶14 - ¶20). As set forth in the Third Declaration, the facts support a conclusion that the methods as disclosed in the Barbachyn et al., reference do not produce the claimed linezolid polymorphic form III, based on a comparison of the XRPD data for the claimed linezolid polymorphic form III, and the linezolid polymorphic form produced using the methods of Barbachyn.

Furthermore, in the Third Declaration under 1.132 of D. Mohan Rao, Ph.D., the methods as disclosed in the Meng reference do not produce the claimed linezolid polymorphic form III, based on a comparison of the XRPD data for the claimed linezolid polymorphic form III, and the XRPD data for the linezolid polymorphic form produced by the methods of Meng. Using the

methods described in the Meng reference, Applicant prepared the linezolid polymorphic form, and evaluated the linezolid polymorphic form produced using XRPD (see Declaration at ¶21 - ¶27). The facts support a conclusion that the methods as disclosed in the Meng reference do not produce the claimed linezolid polymorphic form III, based on a comparison of the XRPD data for the claimed linezolid polymorphic form III, and the linezolid polymorphic form produced using the methods of Meng.

Furthermore, in the Third Declaration under 1.132 of D. Mohan Rao, Ph.D., Applicant shows that the methods as disclosed in the Pearlman reference do not produce the claimed linezolid polymorphic form III, based on a comparison of the XRPD data for the claimed linezolid polymorphic form III, and the XRPD data for the linezolid polymorphic form produced by the methods of Pearlman (see Declaration at ¶28 - ¶34). Using the methods described in the Pearlman reference, Applicant prepared the linezolid polymorphic form, and evaluated the linezolid polymorphic form produced using XRPD. The facts support a conclusion that the methods as disclosed in the Pearlman reference do not produce the claimed linezolid polymorphic form III, based on a comparison of the XRPD data for the claimed linezolid polymorphic form III and the linezolid polymorphic form produced using the methods of Pearlman.

Here, the claims set forth the XRPD data and IR spectra for the claimed linezolid polymorphic Form III, and the claimed Form III linezolid is clearly different from the forms prepared according to the methods as disclosed in any of the Barbachyn, Meng, or Pearlman references. Applicant has demonstrated that XRPD and IR data show the polymorphic forms as taught in the Barbachyn, Meng, and Pearlman references are distinct from the claimed polymorphic form III linezolid. In addition, Applicant has provided a comparison of the DSC thermogram for the claimed linezolid form III polymorph and linezolid form II polymorph, and shown that the melting temperature for linezolid form III is different than that reported in the art for linezolid. Therefore, the assumption that crystallization of linezolid according to the methods as disclosed in Barbachyn, Meng, and Pearlman will yield the same polymorphic form as crystallization according to the method as set forth in the instant application has no basis in fact. Thus, the claimed crystalline Form III linezolid is not disclosed or suggested in any of the Barbachyn, Meng, or Pearlman references.

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Reply to Office Action of 08/21/2009

Accordingly, reconsideration and withdrawal of the rejections of claims 1 and 39 under 35 USC 102(b) is respectfully requested.

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For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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